4811 Strathmore Avenue 9 7 Kensington, MD 20895-1206 OO APR 20 A11:01 April 16, 2000

VIA EMAIL: FDAdockets@fda.gov

Dockets Management Branch (HFA-305) Food and Drug Administration, Room 1061 5630 Fishers Lane Rockville, MD 20852

Re: Docket No. 00N-0598

## Gentlemen:

This letter is written for inclusion in the record on the above-referenced matter. I was unable to attend the public meeting held in Washington, D.C. on April 4, 2000, and appreciate the opportunity to comment on this important issue.

I would like to share a very personal experience I had while taking Metabolife 356 for only 1 week and the continuing symptoms that I still experience. I took Metabolife 356 in accordance with the instructions included in the written material received with my bottle of Metabolife 356. I took only 14 pills over a 1-week period, drank plenty of water, ate food as instructed, and lost no weight. However, as a result of taking this "natural herb" for only 1 week I experienced severe and constant pressure and pain and developed a rapid (arrhythmic) heart beat. I went to see my family physician who immediately referred me to a cardiologist. I remain under the care of a cardiologist now, 6 months after I took my last Metabolife 356 pill.

The label and the literature accompanying Metabolife 356 are deceptive and dangerous. The label leads the general public to believe that this product had been "independently laboratory tested for SAFETY\*" (a fact that the University involved denies). The label indicates that the product contains natural herbs. While, Metabolife 356 does contain natural herbs, the one herb most dangerous-Ma Huang-has speed-like qualities. In fact, the President of Metabolife has a criminal record for drug-related criminal activities involving accelerants, as I understand matters.

When we reported my health problems to Metabolife, we were informed that I was "the only one" who reported health issues after taking the Metabolife product. Nurse Dan Rodriguez thought it was very unusual that my symptoms persisted after I stopped taking Metabolife 356. When we requested a copy of his notes of our telephone conversation, we were told that their attorneys refused to share their notes with us, and he hoped that we were also taking notes of our telephone conversation. I have never had any heart problems UNTIL taking Metabolife 356. Today, my symptoms have not disappeared—some six months after I stopped taking Metabolife 356.

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Metabolife 356 is a very dangerous product, and I urge the FDA to continue its efforts to regulate products of this type. To do otherwise would be irresponsible. The public must be warned about the dangers of Metabolife 356 and other products containing dangerous "natural herbs".

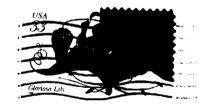
Sincerely,

Carol A. Maryman

cc Michael Ellis, Metabolife International, Inc.
The Honorable Congresswoman Connie Morella
The Honorable Congressman Steny H. Hoyer

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